Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences

-- (Self) Assessment Framework –

January 2020
Working Draft

Culture of Biosafety, Biosecurity, and Responsible Conduct
- Definition[1] -

An assembly of beliefs, attitudes, and patterns of behavior of individuals and organizations that can support, complement or enhance operating procedures, rules, and practices as well as professional standards and ethics designed to prevent the loss, theft, misuse, and diversion of biological agents, related materials, technology or equipment, and the unintentional or intentional exposure to (or release of) biological agents[1].

Culture of Biosafety, Biosecurity, and Responsible Conduct
-Elements-[1]:

I. **Management Systems**
II. **Behavior of Leadership and Personnel**
III. **Principles for Guiding Decisions and Behaviors**
IV. **Beliefs, Opinions, and Attitudes**

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[1] *A Guide to Training and Information Resources on the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences*, 2019, developed by the International Working Group [formerly known as the Federal Experts Security Advisory Panel (FESAP) Working Group] on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences, available online at: https://absa.org/wp-content/uploads/2019/04/CULTURE_TRAINING_CATALOGUE.pdf

Foreword:

This tool intends to provide a measure of the organizational culture of biosafety, biosecurity, and responsible conduct to aid in the process of enhancing such culture at the local level through baseline and periodic assessments.

Benefits of conducting such assessments include gaining and sharing understanding how basic assumptions influence behaviors and performance as they relate to biosafety and biosecurity; providing information on behaviors that contribute to, or undermine biosafety and biosecurity; and gaining an understanding of the impact of culture on organizational performance.

While this is an attempt to adapt the nuclear safety and security culture model[4] to the biological domain, future efforts to holistically integrate characteristics and indicators of an organizational culture across chemical, biological, and radiological/nuclear (CBRN) domains may help establish a framework for holistically assessing the CBRN safety and security culture in laboratories and other related organizations working with such hazardous materials. Such efforts will not be possible without the leadership of major international organizations and the support of professional associations.

Practical tips for using the (Self) Assessment Framework:

- Similar to the nuclear domain and guidance on nuclear safety and security culture issued by the International Atomic Energy Agency (IAEA), organizational culture assessments or self-assessments are best conducted under the guidance of trained, experience individuals and would be most effective with the participation of subject matter experts in psychology, sociology, and organizational behavior.
- While the tool can be used to assess the organizational culture internally with organic staff/support only, using outside subject matter experts would beneficial to combine the results of the survey with documents (records) reviews, observing on-site behaviors, focus group discussions, and interviews.
- Leadership and personnel engagement at all levels that fosters self-exploration and learning about biosafety and biosecurity perceptions and patterns of behavior, is critical to attaining any benefits from such assessment.
- The survey may include a set of questions on the role and responsibility of each respondent (i.e. laboratorian, laboratory supervisor, mid/top level manager), for a more detailed analysis of sub-cultures in an organization.
- While surveys to assess biosafety and biosecurity are not new, this particular tool aims to provide a perspective on the state of culture at the organizational level, based on specific elements of the organizational culture model.
- Numerical/color-coded results obtained post-survey are just a start for further analysis (i.e. red/yellow areas of caution, specific details in open comments, differences in results per categories of respondents, etc.) and a foundation for conducting a SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis[2] to develop a corrective action plan and inform decision-making on strengthening the organizational culture of biosafety, biosecurity, and responsible conduct.

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[2] For a general overview of a SWOT analysis, see: Community Assessment, Section 14. SWOT Analysis: Strengths, Weaknesses, Opportunities, and Threats, online at: https://ctb.ku.edu/en/table-of-contents/assessment/assessing-community-needs-and-resources/swot-analysis/main

- Drilling down with additional surveys, focus group discussions, and interviews may be part of a corrective action plan to address specific weak areas or provide additional granularity to the survey results.[3]
- The (Self) Assessment Framework is a work in progress that can be improved based on feedback from the field, from laboratorians and assessors worldwide; if you would like to submit feedback on using the framework and/or participate in the collective efforts of the International Working Group to improve this framework, contact Dr. Dana Perkins at: dana.perkins@hhs.gov

Survey questions were developed by the members of the International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences, or adapted from the references below. Select references included here can be used on their own for additional assessments.

- *Nuclear Security Culture: Implementing Guide*, International Atomic Energy Agency, 2008[4].
- *Biorisk Management Survey*, Sandia National Laboratories[5]
- *Responsible life sciences research for global health security*, WHO, 2010[6]
- *An analytical approach for the development of a national biosafety and biosecurity system*, 2nd ed., Public Health Agency of Canada, 2010[7]
- *Biosecurity Self-Scan Toolkit*[8] and the *Vulnerability Scan* developed by the National Institute for Public Health and the Environment / Biosecurity Office- The Netherlands.

This framework aims to assess the culture of biosafety, biosecurity, and responsible conduct at the organizational level. Other tools have different aims and purposes and may have areas overlapping with this framework (e.g. WHO's Joint External Evaluations, ISO 35001:2019 *Biorisk management for laboratories and other related organizations*[9], and others.

The International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences includes representatives from the following organizations:
U.S. Department of Health and Human Services [Centers for Disease Control and Prevention (CDC); Food and Drug Administration (FDA); National Institutes of Health (NIH); Office of the Assistant Secretary for Preparedness and Response (ASPR)]; U.S. Department of Agriculture, U.S. Department of Defense, U.S. Department of Homeland Security, Federal Bureau of Investigation (FBI), Environmental Protection

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[3] For instance, with regard to education and level of awareness, Professor Malcolm Dando (University of Bradford, UK) suggests additional questions such as: *How will the present state of knowledge about dual use of members of the organization be assessed; What will be the content (curriculum) of this educational program; How will the course material be produced; By what method(s) will this educational material be conveyed to participants; How and who will deliver the training material; How will participation in this educational program be ensured and assessed; How will be impact of the educational program be evaluated.*

[4] *Nuclear Security Culture: Implementing Guide*, IAEA, 2008, https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1347_web.pdf

[5] *Summary of the East Africa Training Consortium Biorisk Management Practices and Training Needs Survey,* Wilder J.A., Mancini G.M., Wakabi T. and Boggs S.E., March 2017, Sandia Report SAND2017-3170, prepared by Sandia National laboratories, https://ohcea.org/images/news/reports/SAND_Report_Summary_of_BRM_Practices_and_Training_Needs_Survey_Final_for_OHCEA.pdf

[6] *Responsible life sciences research for global health security- A Guidance Document*, 2010, WHO, https://apps.who.int/iris/bitstream/handle/10665/70507/WHO_HSE_GAR_BDP_2010.2_eng.pdf;jsessionid=E1B2BC97ED6233DD97EA733B2D6A2940?sequence=1

[7] *An Analytical Approach for the Development of a National Biosafety and Biosecurity System*, training course developed by the Public Health Agency of Canada, https://training-formation.phac-aspc.gc.ca/course/index.php?categoryid=49

[8] Biosecurity Toolkits developed by the National Institute for Public Health and the Environment / Biosecurity Office- The Netherlands, https://www.bureaubiosecurity.nl/en/toolkit

[9] *ISO 35001:2019 Biorisk management for laboratories and other related organisations,* https://www.iso.org/standard/71293.html

Agency (EPA), U.S. Department of Energy, U.S. Department of Interior, INTERPOL, World Health Organization (WHO), World Organization for Animal Health (OIE), Biological Weapons Convention Implementation Support Unit (BWC ISU), Royal Scientific Society of Jordan, National Institute for Public Health and the Environment / Biosecurity Office- The Netherlands, Centre for Biosecurity and Biopreparedness – Denmark, DSTL (UK), PHAC (Canada), U.S. National Laboratories [National Biodefense Analysis and Countermeasures Center (NBACC); Pacific Northwest National Laboratories (PNNL); Sandia National Laboratories], National Academies of Sciences, Engineering, and Medicine (US); ABSA International, American Association for Laboratory Animal Science (AALAS), American Society of Microbiology (ASM), Association of Public Health Laboratories (APHL), European Biosafety Association (EBSA), International Federation of Biosafety Associations (IFBA), The University of Texas Medical Branch at Galveston University (UTMB), Colorado State University, North Carolina State University, Emory University, University of Massachusetts Dartmouth, University of Chicago, Bradford University (UK), MedImmune, AECOM, BioSecure (UK), Health Security Partners, iGEM Foundation, GenSpace, Baltimore Underground Science Space (BUGSS), CHROME Biosafety and Biosecurity Consulting, Safer Behaviors LLC, Gryphon Scientific, Center for the Study of Democracy (Bulgaria), B & S Europe, Emlyon Business School (France).

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Survey Questions:

The respondents have a Likert scale range of options to express their current view of the organizational culture of biosafety, biosecurity, and responsible conduct. The 0-5 numerical values allow for each element of culture to be assessed as an average percentage and for raw data to be collected and analyzed.

The assessor(s) may correlate the numerical values with a color scale to give a visual on the current status of each culture element: 0-1-red, 2-3- yellow, and 4-5- green.

Examples of the overall calculations for the assessment are provided in the next section.

Roles /job categories

Laboratory worker (scientist, engineer, technician)	Administrative and support staff	Laboratory Supervisor	Mid and top level manager	Others
☐	☐	☐	☐	☐

I. Management Systems

An organizational culture of biosafety, biosecurity, and responsible conduct in the life sciences includes policies, processes, procedures, and programs in the organization that make biosafety and biosecurity a top priority and have an important impact on biorisk management functions.

Examples include but are not limited to:
• Clear roles and responsibilities
• Visible safety and security policy
• Performance measurement
• Feedback process
• Competency-based training and competency verification
• Compliance checks/implementation

	I. ***Management Systems***	N/A or I don't know	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree	FOR ASSESSOR TEAM USE ONLY Color Scale 0-1-red, 2-3-yellow, and 4-5- green
1	My organization has procedures in place to keep employees informed on the risks of unintentional and/or intentional release of, or exposure to, biological agents and/or toxins that are stored or handled at our facilities.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
2	My organization publicly explains the procedures and rules of conduct related to biosafety and biosecurity during new employee orientation.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
3	My organization has a systematic risk-benefit analysis process in place for dual-use research.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
4	The organization has mitigation procedures in place to reduce the risk of unintentional and/or intentional release of, or exposure to, biological agents and/or toxins stored or handled at our facility.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
5	My organization has implemented mitigation procedures to reduce the risk of unintentional and/or intentional release of, or exposure to, biological agents and/or toxins stored or handled at our facilities.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
6	My organization has procedures in place which detail the actions required during an incident.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
7	Lessons learned from emergency drills have improved organizational performance.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
8	My organization conducts emergency response drills on a regular basis.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
9	There is an up-to-date list available of personnel with authorized access to biological agents.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
10	Utilizing lessons learned from emergency drills has improved organizational performance.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
11	There is a procedure in place for employees to report unusual behavior in a co-worker.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
12	Utilizing lessons learned from biosafety/biosecurity violations or near misses has improved organizational performance.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
13	There is an available and up-to-date list of personnel authorized to access biological agents.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
14	The organization has continuing biosafety and biosecurity education and competency training for employees.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
15	Information regarding biosafety and biosecurity measures, procedures, and policies is readily available to employees.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	

16	There is a procedure in place for employees to report a coworker's unusual behavior.	☐ **0**	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**	
17	There is an established internal communication procedure to inform employees about biosafety and biosecurity incidents and near misses.	☐ **0**	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**	
18	Individual biosafety/biosecurity performance assessments occur on a regular basis.	☐ **0**	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**	
19	There are procedures in place for decontamination and waste management.	☐ **0**	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**	
20	Prior to being granted access to pathogens and toxins, workers are screened for appropriate credentials, skills, and personal traits for the job, and determined to be the best fit for the position.[7]	☐ **0**	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**	

Management Systems -- Additional comments:

II. Behavior of Leadership and Personnel

Leadership behavior (i.e., specific patterns of behavior and actions of leadership, including supervisors, mid- and top-level managers, which are designed to foster more effective biorisk management) should emphasize among other things:

• Expectations
• Decision-making
• Oversight
• Effective communication
• Motivation
• Inspiration/building trust

Personnel behavior (the desired outcomes of the leadership efforts and the operation of the management systems) should underscore among other things:

• Professional conduct
• Adherence to approved/validated procedures and research protocols
• Team work and cooperation
• Vigilance

	II. Behavior of Leadership and Personnel	N/A or I don't know	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree	FOR ASSESSOR TEAM USE ONLY Color Scale 0-1-red, 2-3-yellow, and 4-5- green
1	Leaders regularly communicate with employees about the risks of unintentional and/or intentional release of, or exposure to, biological agents and/or toxins stored or handled at my facility.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
2	Leaders regularly communicate with employees about the measures in place to reduce the risks of unintentional and/or intentional release of, or exposure to, biological agents and/or toxins stored or handled at my facility.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
3	My supervisor/manager sets a good personal example of practices aimed at reducing biohazards risks.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
4	Leaders monitor adherence to the approved/validated procedures (or research protocols) and rules of conduct.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
5	Leaders provide the required means to implement biosafety and biosecurity measures	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
6	Leaders in my organization encourage employees to increase their education and awareness of biohazards risks.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
7	I feel confident that I can self- report illness or other conditions that may affect biosafety/biosecurity without fear of losing my job nor other negative effects on my working life/career	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
8	It is never appropriate to tag along ("piggyback") with an employee who is authorized to gain entry into a restricted area.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
9	I do/would/will report unusual behavior of my colleagues that increases the risk of unintentional and/or intentional release of, or exposure to, biological agents and/or toxins.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
10	I am involved in risk assessment and decision making processes to reduce the risk of unintentional and/or intentional release of, or exposure to, biological agents and/or toxins stored or handled at my facility	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
11	My organization values vigilance on biosafety and biosecurity.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
12	In my organization there are measures in place to punish willful violations of biosafety and biosecurity.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
13	Leaders communicate with staff about specific performance expectations in areas that affect biosafety and biosecurity	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
14	Employees are involved in the risk assessment and decision making processes and other activities that affect them.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
15	Everyone in my facility properly disposes of contaminated materials.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
16	Behavior that enhances biosafety and biosecurity culture is reinforced by my peers.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
17	I don't/wouldn't/won't not perform research without proper risk mitigation measures in place.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	

	II. **Behavior of Leadership and Personnel**	N/A or I don't know	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree	FOR ASSESSOR TEAM USE ONLY Color Scale 0-1-red, 2-3-yellow, and 4-5- green
18	Leaders/managers make themselves approachable, allow effective two way communication, and encourage staff to report concerns or suspicions without fear of subsequently suffering disciplinary actions.[4]	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
19	I do/would/will report incidences of unauthorized or improperly/inadequately trained personnel accessing the facility.[7]	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
20	Leaders/managers encourage, recognize, and reward commendable attitudes and behavior.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	

Behavior of Leadership and Personnel -- Additional comments:

III.   Principles for Guiding Decisions and Behaviors

Emphasis should be placed on principles for guiding decisions and behaviors as they relate to biorisk management. Examples include but are not limited to:

• Leadership
• Commitment and responsibility
• Professionalism and competence
• Learning and improvement
• Maintaining public trust
• Codes of conduct (including codes of ethics)[10]

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[10] For a review of relevant codes of conduct see: *Promoting responsible science and CBRN security through codes of conduct and education,* Novossiolova T. & Martelini M., Biosafety and Health Volume 1, Issue 2, September 2019, Pages 59-64, https://doi.org/10.1016/j.bsheal.2019.08.001

	III. *Principles for Guiding Decisions and Behaviors*	N/A or I don't know	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree	FOR ASSESSOR TEAM USE ONLY Color Scale 0-1-red, 2-3-yellow, and 4-5- green
1	Encouragement and reinforcement received from leaders, peers and subordinates significantly influences work performance.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
2	My organization reinforces ethical norms and a professional code of conduct.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
3	Leaders in my organization demonstrate their commitment to biosafety and biosecurity through words and actions.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
4	My organization applies lessons learned and best practices.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
5	My organization has an Insider Threat mitigation program.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
6	My organization promotes public transparency with regard to its compliance with biosafety and biosecurity requirements.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
7	Everyone shares personal responsibility for biosafety and biosecurity.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
8	I am aware of the concept and implications of dual use research of concern.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
9	Appropriately qualified and trained individuals provide oversight on biosafety and biosecurity	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
10	When an incident or near miss occurs, there is 'brainstorming' not 'blamestorming'. The question asked is "*what went wrong?*" not "*who was wrong?*", focusing on improvement, not blame.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
11	I consider the implications and possible applications of my work and the balance between the pursuit of scientific knowledge and my ethical responsibilities to society.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
12	I am motivated to minimize risks of the misuse of science for society.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
13	I am cognizant of the threat of bioterrorism and biological weapons.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
14	My organization has a code of responsible conduct in place.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
15	Standards are enforced in my organization.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
16	Admitting mistakes, taking ownership, and developing a plan to overcome challenges and/or implement corrective actions are integral to effective biosafety and biosecurity.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
17	I strive for professional excellence through self-assessment and continuing education.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
18	I always report data with integrity and accuracy.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
19	I always comply with all laws, regulations, policies, and standards governing the life sciences practice.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
20	Potential for misuse of the research is considered at all stages, and appropriate action is taken if necessary.[6]	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	

Principles for Guiding Decisions and Behaviors -- Additional comments:

IV.   Beliefs, Opinions, and Attitudes

Beliefs and attitudes on biosafety and biosecurity (including on dual use research of concern and cyberbiosecurity) should be assessed periodically and reinforced through training and education aiming to:

• Raise awareness on consequences and mitigation strategies of risks associated with working in a laboratory with biological materials (e.g., accidental exposure, infection or release; intentional theft and/or misuse; others such as cybersecurity, radiological/chemical/physical safety and security)
• Increase understanding of the ethical, legal, and societal issues and consequences concerning life sciences research, development, and associated technologies
• Emphasize laboratory quality management
• Ensure compliance with regulations, policies, guidance, and procedures.

	IV. Beliefs, Opinions, and Attitudes	N/A or I don't know	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree	FOR ASSESSOR TEAM USE ONLY Color Scale 0-1-red, 2-3-yellow, and 4-5- green
1	There is a risk of bioterrorism or an attack with a biological weapon.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
2	Controlling access to sensitive information is integral to biosecurity.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
3	I understand the importance of trustworthiness determination.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
4	My organization provides training on identifying symptoms of high-risk behavior in oneself and in others.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
5	Biosafety and/or biosecurity deficiencies or vulnerabilities are corrected with a sense of urgency.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
6	I take professional pride in my work.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
7	My organization and its members encourage teamwork and cooperation.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
8	Biosafety and biosecurity infractions are handled appropriately.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
9	My organization cares more about biosafety than about the results of our work.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
10	I am aware that there are ethical, legal, and societal issues and consequences attached to my research.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
11	Technical expertise and experience underpin the assurance of future biosafety performance.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
12	In my organization, individuals have appropriate competency to perform their assigned tasks and to work safely and effectively.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
13	My organization has a culture that supports and encourages trust, collaboration, consultation, and communication with regard to biosafety and biosecurity.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
14	National policy and legislation relevant to the life sciences aim to provide protection against the misuse of science.[6]	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
15	Risk assessments are important tools to identify areas of improvement and specific measures for reducing risk, including the level of containment required.[6]	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
16	I believe that it is important to report not only laboratory accidents and incidents but also near misses.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
17	I have received adequate training on the procedures necessary to conduct my work without compromising safety and security.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
18	I have adequate PPE available for me to perform my work safely and securely.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
19	Scientists have an obligation to do no harm.[11]	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
20	I do/would/will report my concerns to the appropriate people, authorities, and/or agencies if I become aware of activities that violate the Biological and Toxin Convention, United Nations Security Council resolution 1540, or international customary law.[9]	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	

Beliefs, Opinions, and Attitudes -- Additional comments:

Example of Numerical Calculation and Color Coding:

	I. Management Systems	N/A or I don't know	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree	FOR ASSESSOR TEAM USE ONLY Color Scale 0-1-red, 2-3-yellow, and 4-5- green
1	My organization has procedures in place to keep employees informed on the risks of unintentional and/or intentional release of, or exposure to, biological agents and/or toxins that are stored or handled at our facilities.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☒ 5	🟩
2	My organization publicly explains the procedures and rules of conduct related to biosafety and biosecurity during new employee orientation.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☒ 5	🟩
3	My organization has a systematic risk-benefit analysis process in place for dual-use research.	☐ 0	☐ 1	☐ 2	☐ 3	☒ 4	☐ 5	🟩
4	The organization has mitigation procedures in place to reduce the risk of unintentional and/or intentional release of, or exposure to, biological agents and/or toxins stored or handled at our facility.	☐ 0	☐ 1	☐ 2	☒ 3	☐ 4	☐ 5	🟨
5	My organization has implemented mitigation procedures to reduce the risk of unintentional and/or intentional release of, or exposure to, biological agents and/or toxins stored or handled at our facilities.	☐ 0	☐ 1	☐ 2	☒ 3	☐ 4	☐ 5	🟨
6	My organization has procedures in place which detail the actions required during an incident.	☐ 0	☐ 1	☐ 2	☐ 3	☒ 4	☐ 5	🟩
7	Lessons learned from emergency drills have improved organizational performance.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☒ 5	🟩
8	My organization conducts emergency response drills on a regular basis.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☒ 5	🟩

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[11] InterAcademy Panel Statement on Biosecurity, 2005, https://www.interacademies.org/13912/IAP-Statement-on-Biosecurity

#	Statement	0	1	2	3	4	5	
9	There is an up-to-date list available of personnel with authorized access to biological agents.	☐	☐	☐	☐	☒	☐	🟩
10	Utilizing lessons learned from emergency drills has improved organizational performance.	☐	☐	☐	☐	☒	☐	🟩
11	There is a procedure in place for employees to report unusual behavior in a co-worker.	☐	☐	☒	☐	☐	☐	🟨
12	Utilizing lessons learned from biosafety/biosecurity violations or near misses has improved organizational performance.	☐	☐	☒	☐	☐	☐	🟨
13	There is an available and up-to-date list of personnel authorized to access biological agents.	☐	☐	☒	☐	☐	☐	🟨
14	The organization has continuing biosafety and biosecurity education and competency training for employees.	☐	☐	☒	☐	☐	☐	🟨
15	Information regarding biosafety and biosecurity measures, procedures, and policies is readily available to employees.	☒	☐	☐	☐	☐	☐	🟥
16	There is a procedure in place for employees to report a coworker's unusual behavior.	☒	☐	☐	☐	☐	☐	🟥
17	There is an established internal communication procedure to inform employees about biosafety and biosecurity incidents and near misses.	☐	☒	☐	☐	☐	☐	🟥
18	Individual biosafety/biosecurity performance assessments occur on a regular basis.	☐	☒	☐	☐	☐	☐	🟥
19	There are procedures in place for decontamination and waste management.	☐	☐	☒	☐	☐	☐	🟨
20	Prior to being granted access to pathogens and toxins, workers are screened for appropriate credentials, skills, and personal traits for the job, and determined to be the best fit for the position.[7]	☐	☐	☐	☒	☐	☐	🟨

Total Score Achieved (sum of numerical responses for the 20 questions): 57
Maximum Achievable Score: 20 x 5 = 100
Final Percentage: Total Score Achieved / Maximum Achievable Score x 100
57 / 100 x 100 = 57%

Total Score: 57%

↓

Overall assessment for *Management Systems*:

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

(Improvement needed) ←——————————————————→ **(Excellent)**
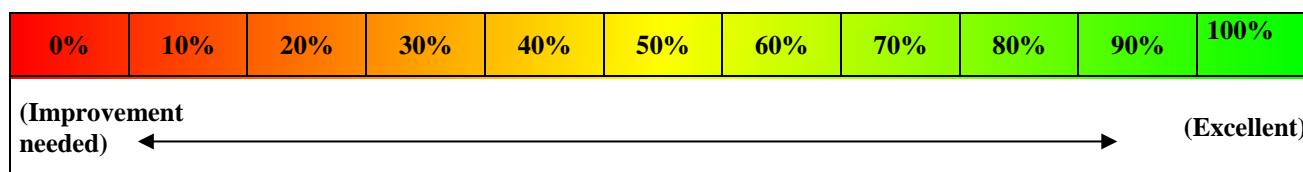
- Perform the same calculations for each of the four elements for the same respondent

- Calculate the average score for all respondents per each element (and/or per category of respondents, e.g. laboratorian, lab supervisor, mid/top level manager, other) and color code.
- Use the Excel template provided as a companion to this framework to create radar/spider charts for an additional way to visualize and present the results.
- Analyze the results of the survey in connection with data obtained from documents (records) reviews, observations of on-site behaviors, focus group discussions, and interviews.
- Conduct a SWOT analysis of the survey results (develop the SWOT matrix, look for potential connections between the quadrants of your matrix, i.e. how can you use identified strengths to take advantage of opportunities or avoid threats, how can you minimize weaknesses by taking advantage of opportunities, etc.).
- Develop recommendations and/or corrective action plans.

Example: Overall Culture Assessment and General Interpretation (red: 0%-40% (improvement needed); yellow: 41-60% (caution); green: 61-100% (adequate to excellent)

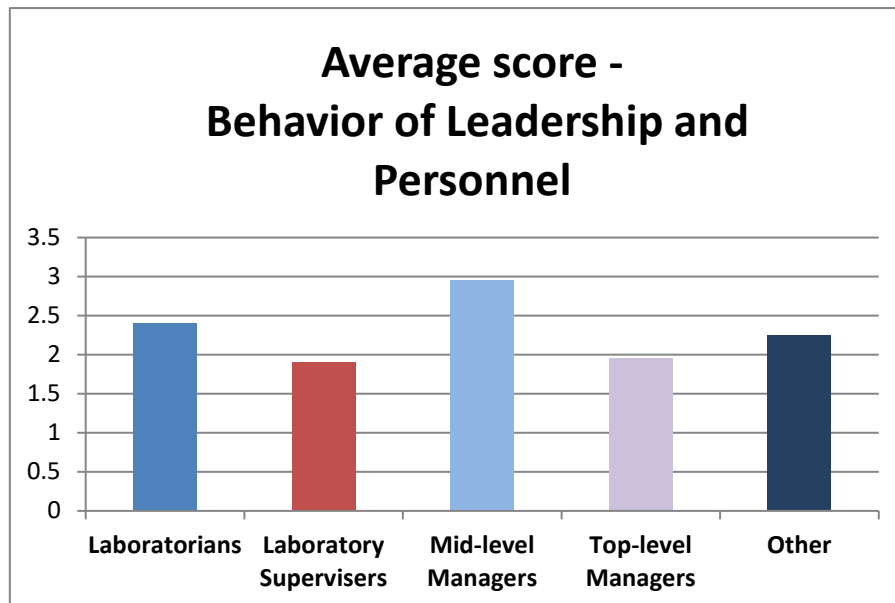| *Management Systems [YELLOW}*	*Behavior of Leadership and Personnel [YELLOW]*	*Principles for Guiding Decisions and Behaviors [RED}*	*Beliefs and Attitudes [GREEN]*
▪ **Element flagged for concern** ▪ **Actions should be considered to boost endorsement of a positive culture of biosafety, biosecurity, and responsible conduct**	▪ **Element flagged for concern** ▪ **Actions should be considered to boost endorsement of a positive culture of biosafety, biosecurity, and responsible conduct**	▪ **Element of great concern** ▪ **Corrective actions should be taken ASAP**	▪ **Adequate or excellent element** ▪ **There may still be room for improvement upon further data analysis** ▪ **Maintenance/sustainability actions recommended.**

Example: SWOT Analysis Matrix to be developed based on survey results

STRENGTHS	WEAKNESSES
1. … 2. … 3. …	1… 2… 3…
OPPORTUNITIES	**THREATS**
1. … 2. … 3. …	1. … 2. … 3. …

Example: Radar/spider chart based on survey results for top-level managers

Behavior of Leadership and Personnel
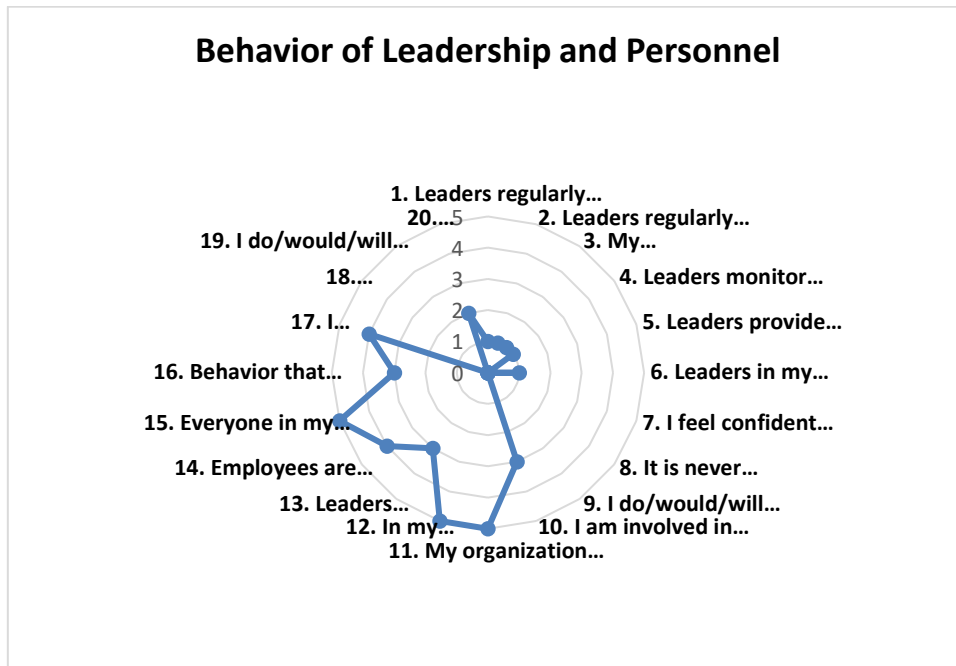
Example: Average scores per job category

**Average score -
Behavior of Leadership and Personnel**

Average Scores by Job Category

— Management Systems
— Behavior of Leadership and Personnel
— Principles for Guiding Decisions and Behaviors
— Beliefs, Opinions, and Attitudes

✳ ✳ ✳